

IRRADIATION Q's & A's

LABELING ISSUES

1. Is the Agency reviewing labels for irradiated products or products containing an irradiated meat or poultry component or can such labels be generically approved?

Such labels must be evaluated by FSIS's Labeling Consumer Protection Staff (LCPS), Labeling Compliance Team (LCT), for an initial sketch approval. Subsequent changes permitted by the generic labeling regulations (9 CFR 317.5 and 381.133) do not require re-approval through FSIS. However, FSIS will be tracking the types and numbers of labels for irradiated products and products containing irradiated meat or poultry ingredients for possible future rulemaking.

2. Does the radura (irradiation logo) have to be green as was previously required by the poultry regulations?

No. There are no longer any specific color requirements. However, other countries may have different or additional requirements for importation of irradiated products.

3. Are the labeling requirements for irradiated poultry the same as those for beef?

Yes. The labeling requirements are identical for meat and poultry products with respect to irradiation.

4. When "irradiated" is part of the product name, e.g., "Irradiated Beef," what other irradiation labeling is required?

The product labeling also must bear the radura.

5. If a label bears the radura and a "treated with radiation" statement, but, the company chooses to put the term "irradiated" with the product name, e.g., "irradiated beef patties," does the term "irradiated" become part of the product name and need to be one third the size of the largest letter in the product name?

Yes. Even though, in this case, the term "irradiated" is not required as part of the product name, if a company chooses to include "irradiated" as

part of the product name, the product name sizing rules (i.e., no letter in the product name can be less than one third the size of the largest letter in the product name.) will apply.

6. How can irradiated beef be identified in the ingredients statement of a multi-ingredient product?

Irradiated beef can be listed in the ingredients statement either as "Irradiated beef," or "Beef, treated by irradiation." The acceptability of similar identifications of irradiated ingredients will be handled on a case-by-case basis.

7. If a beef carcass is irradiated and then broken down into primal and retail cuts, how would the primal and retail cuts be labeled?

The labeling of all single-ingredients products made from an irradiated carcass must bear the radura and either the term "irradiated" as part of the product name or the inclusion of a statement, such as, "Treated with Radiation" or "Treated by Irradiation." Such labeling would also be required at the grocery store for product that is packaged and placed in the display counter for consumers.

8. What are the requirements for labeling bulk irradiated product at retail, e.g., irradiated beef in a butcher shop?

Point of purchase identification of an irradiated meat or poultry product can be by a label on the package or by the use of placards or brochures located next to the product.

9. If ground beef is manufactured from irradiated beef or irradiated beef trimmings, would it be labeled as "Ground Irradiated Beef?"

The product labeling would be required to include the radura and a statement, such as, "Treated with Radiation" or "Treated by Irradiation." If "irradiated" is part of the product name, e.g., "Ground Irradiated Beef," or "Irradiated Ground Beef," the statement is not required. Additionally, labeling a product as "Ground Irradiated Beef" still requires the product must meet the standard for ground beef.

10. How would a ground beef product be labeled if it was a combination of irradiated beef and non-irradiated beef?

All that would be required on the label would be to list "beef" and "irradiated beef" or "beef, treated by irradiation" in the ingredients statement. However, in addition to the ingredients statement declaration, the product label could include the radura and the required statement or the radura and a product name which indicated the combination, e.g.,

“Irradiated Ground Beef and Ground Beef,” or “Ground Beef and Irradiated Ground Beef,” depending on the order of predominance.

11. What is the proper way to label a fabricated multi-ingredient product, e.g., fresh sausage, made with only non-fluid seasonings and irradiated beef, which is then packaged and irradiated?

The fresh sausage label would bear the radura and either be labeled as “irradiated” sausage or contain a required statement, such as, “Treated with radiation” or “Treated by irradiation.” Secondly, the sausage ingredients statement would identify the beef as either “Irradiated beef” or “Beef, treated by irradiation.”

12. Would an irradiated meat or poultry component used in a multi-ingredient product need to be labeled as “irradiated” in the ingredients statement of the multi-ingredient product, if the finished product is also irradiated?

Yes.

13. Do point-of-purchase labeling requirements apply to restaurants?

No. There are no labeling requirements for irradiated products at restaurants. However, FSIS is aware of several restaurants that voluntarily disclose irradiation information on menus and encourages this type of disclosure.

14. What labeling statements about the purpose of radiation processing have been authorized for use on labeling in conjunction with the radura in addition to or instead of “Treated with radiation” or “Treated by irradiation?”

FSIS has reviewed and approved the following statements:

“Treated with irradiation for your food safety”
“Treated with irradiation for food safety”
“Treated with irradiation to improve food safety”
“Treated with irradiation to reduce the potential for foodborne illness”
“Treated with irradiation to reduce *E. coli* bacteria”
“Treated with irradiation to reduce pathogens such as *E. coli* and *Salmonella*”
“Irradiated for your food safety”
“Irradiated for food safety”

15. Would FSIS consider the term “pasteurized” as an acceptable term to describe the irradiation process?

At this time, labeling statements or claims for irradiated products that include the term “pasteurization” are misleading. FSIS will continue to

examine this term in light of developments in irradiation technology and FDA policy. In the future, use of the term "pasteurization" will be considered on a case-by-case basis and would require significant documentation and validation as to process controls that demonstrate that vegetative cells of pathogens have been reduced to safe levels and produces a ready-to-eat product.

16. We are aware that steam-pasteurization is currently permitted, and that labeling can state that the product was steam-pasteurized. Why is the phrase permitted on such product if not permitted on irradiated product?

The use of steam-pasteurization is only permitted for whole carcasses and parts of carcasses that are to be further processed. Moreover, the labeling of further processed products, such as retail cuts (e.g., ground beef, steaks) and offal (e.g., tripe, intestines, etc.) with statements about reductions in microorganisms or the use of the term "steam-pasteurized" is not permitted because it is misleading to consumers.

17. Can the terms "all," "pure," and "100%" be used on irradiated beef?

Yes. The regulations in 9 CFR 317.8(b)(34) and 381.129(b)(5) specify the terms "all," "pure," "100%," and terms of similar connotation shall not be used on labels for products to identify ingredient content unless the product is prepared solely from a single ingredient. Thus, irradiated, single ingredient meat or poultry can be labeled in this manner.

18. Is a "No MSG Added" claim acceptable on irradiated ground beef?

Since MSG is not classified as a non-fluid seasoning, it is not permitted to be in a product that is subsequently irradiated. Therefore, a "no MSG added" claim is a "negative claim" and may only be used if accompanied by the statement "USDA regulations do not permit the addition of MSG to irradiated products."

19. Can an irradiated product be labeled as "natural" or "certified Organic by (a certifying entity)?"

The term "natural" can not be used since FSIS considers irradiation to be more than minimal processing. Thus, such products would not meet the "natural" criteria established by Policy Memo 55. Regarding the use of "certified Organic by (a certifying entity)," we are not aware of any organization providing organic certification that allows the use of irradiation. Further, on March 13, 2000, AMS issued a re-proposed regulation on organic agricultural products which does not permit the use of irradiation on products labeled "organic."

20. How can a company label a box containing a variety of meat or poultry products including some that are irradiated and some that are not irradiated?

It must be perfectly clear to consumers which products are irradiated and which products are not irradiated. The best method of conveying this information is to include “irradiated” as part of the product name on the principal display panel of all irradiated products as well as the radura on the label.

21. Does the labeling of the shipping container of irradiated products require inclusion of the radura and other required information?

Not for a true shipper that is only labeled with the inspection legend and a handling statement, if necessary, and that holds fully labeled products.

22. Can whole livestock blood (dried or fluid) be irradiated?

Yes. Whole blood is considered a byproduct which can be irradiated provided it does not contain additives, e.g., sodium citrate as an anticoagulant.

INGREDIENT ISSUES

1. Consider this situation: A company intends to use irradiated beef in its beef patty; however, it is concerned about the availability of the irradiated beef component. Can the company use “and/or” or “may contain” labeling with respect to the irradiated beef component?

No. Consumers wishing to purchase products containing an irradiated meat component consider the irradiated meat to be a “valuable” constituent of the finished product. FSIS labeling regulations do not include provisions for “and/or” labeling and policies have not permitted the use of a “may contain” statement in reference to a “valuable” component, e.g., truffles, veal, etc. FSIS policies have only permitted the use of a “may contain” statement with “minor” ingredients, generally under two percent of the total formulation, that do not affect the character of the product. FSIS has never considered the meat or poultry components to be classified to be “minor” in this situation.

2. What are non-fluid seasonings?

Non-fluid seasonings are dried spices, e.g., thyme and basil, dried flavorings from botanical sources, e.g., garlic powder and lemon powder, salt and sugar. Ingredients such as MSG, autolyzed yeast extract, hydrolyzed (source) proteins, and garlic have not been considered to be non-fluid seasonings. For example, whole garlic is a vegetable, not a spice, while garlic powder is a spice/seasoning.

3. If non-meat/non-poultry ingredients, such as irradiated spices, wheat flour, potatoes, and fruits, are added to an irradiated or non-irradiated meat/poultry product, must the fact that they have been irradiated be disclosed in the ingredients statement?

No. However we would permit this ingredient statement identification for irradiated non-meat and non-poultry components.

4. For the purposes of irradiation, are ingredients such as BHA, BHT, TBHQ permitted in sausage products that will be irradiated?

At this time, no.

PACKAGING MATERIAL ISSUES

1. Do poultry products that are packaged and irradiated still need to be packaged in air permeable packaging materials?

Yes, until FDA issues a final rule that no longer mandates the use of air permeable packaging materials for irradiated poultry products. However, poultry that is irradiated and packaged after irradiation is not required to be packaged in air permeable packaging materials.

2. If meat and poultry are packaged together and irradiated, would they need to be packaged in air permeable packaging materials?

Yes. While red meat alone is not required to be packaged in air permeable packaging materials if packaged prior to irradiation, because that requirement still exists for poultry, a combination, e.g., beef roast and chicken breast packaged together prior to irradiation would have to be packaged in air permeable packaging materials.

3. Can meat irradiated with electron beam be packaged in the same packaging materials as meat irradiated by gamma ray?

Yes. Recently, FDA provided approval on a trial basis (until February 22, 2001) to permit any of the materials currently approved under 21 CFR 179.45 to be used when pre-packaged meat food and poultry food products are treated with X-ray, electron beam and gamma ray irradiation under the following conditions:

- a. “The irradiation processor will comply with all general provisions for food irradiation listed in sections CFR 179.25 and 21 CFR 179.26(b);
- b. The machine sources of X-radiation and electron beams are used at dose levels not to exceed that specified in section 21 CFR 179.45 for packaging materials used, and at dose levels not to exceed those specified in 21 CFR 179.26(b) for the foods packaged;
- c. With the exception of the radiation source, as noted above, the packaging materials must comply with all other provisions of 9 CFR 179.45; and
- d. FSIS will monitor the participating establishments and immediately inform FDA of any unexpected findings.”

PROCEDURAL ISSUES

1. Can hot-boned meat or poultry be irradiated?

As of today, no. The regulation covers only refrigerated or frozen product. However, FSIS has petitioned FDA to allow the irradiation of hot-boned meat and poultry.

2. Will USDA accept imported meat and poultry products that have been irradiated in other countries into the US for distribution?

Yes, provided they were treated and labeled consistent with USDA regulations.

3. If a company has its product irradiated, at another facility, must the HACCP plan at the producing establishment incorporate the irradiation step and CCP, or can there be two separate plans, i.e., one at the producing establishment and one at the irradiation establishment?

FSIS considers any firm that irradiates meat food or poultry products to be an official establishment. Official establishments are required to irradiate meat food and poultry products only in accordance with HACCP systems. If an establishment contracts for its products to be irradiated for the purpose of reducing pathogens, we expect that establishment to have a CCP in its HACCP plan for irradiation, even though it does not conduct the irradiation in its own facility. Through review of receipts, certificates, and other records provided by the irradiator, the establishment would monitor and verify that its product was irradiated in accordance with its HACCP plan, contractual specifications, and the regulations. We also expect an establishments that has contracted out irradiation to address hazards it has identified to complete and sign its pre-shipment review only after verifying that its products have received the appropriate irradiation treatment by the contractor.

4. Can meat be irradiated more than one time?

Yes, but the total permitted absorbed dosage can not be exceeded. In these situations, it is the responsibility of the manufacturer to maintain records to document permissible limits are not exceeded.

5. What can be done with products that inadvertently receive too high an irradiation dosage?

The products must be condemned as inedible and denatured.

6. Are there special concerns with a fabricated multi-ingredient product, e.g., fresh sausage, made with only seasonings and irradiated beef, which is then packaged and irradiated?

Yes. Total dosage of irradiation permitted for beef and other components, e.g., spices, could not be exceeded. Additional recordkeeping would probably be necessary to ensure that the maximum absorbed dosage is not exceeded.